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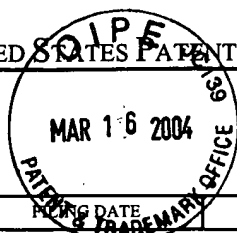
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,142	12/08/2000	Bernard Charles Sherman	PT-1877000	5119

23607 7590 02/12/2004

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EXAMINER

SPEAR, JAMES M

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 02/12/2004

Determination of Patent Term Extension under 35 U.S.C. 154 (b)
(application filed after June 7, 1995 but prior to May 29, 2000)

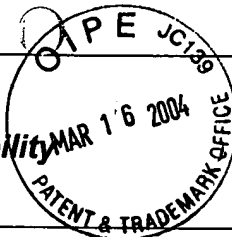
The Patent Term Extension is 0 day(s). Any patent to issue from the above-identified application will include an indication of the 0 day extension on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Extension is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) system (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (703) 305-1383. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

Notice of Allowability



Application No.

09/719,142

Examiner

James M Spear

Applicant(s)

SHERMAN, BERNARD CHARLES

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to November 21, 2003.
2. ☒ The allowed claim(s) is/are 1-11.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

James M. Spear

James M Spear
Primary Examiner
Art Unit: 1615

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1. The following is an examiner's statement of reasons for allowance:
 - a. The declarations submitted November 21, 2003 have been considered.
 - b. Applicants show a pharmaceutical tablet wherein two smaller tablets comprised of an NSAID and misoprostol are incorporated in said tablet such that contact between the two is at a minimum. The prior art shows tablets comprised of the combination of the two drugs. Sims, Stuerzebecher and Kararli as cited in prior actions and considered the closest prior art of record show such combinations. The prior art does not show nor fairly suggest applicant's particular tablet combination wherein a covering characterized by applicant's shell provides a distinct structured tablet. While the prior art shows coatings to protect tablet comprised of granules, the prior art does not show 2 tablets within a tablet where the active agents have minimal contact. Applicant's embedded tablets in carrier components as opposed to coated tablets optimize stability. The shell comprised of powder or granular mixture is dispersed around the embedded tablets and is not a homogeneous coating comprised of dissolved components. The shell in turn being a distinct structure minimizes contact between the 2 actives and does not exhibit surface exposure of the drugs, as would a coating.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."


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Claims 1-11 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James M Spear whose telephone number is 571 272 0605. The examiner can normally be reached on Monday thru Friday from 6:30 AM to 3 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page, can be reached on 571 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


James M Spear
Primary Examiner
Art Unit 1615

February 7, 2004

PRIOR AMENDMENTS TO THE CLAIMS

Claim 1 (previously amended): A pharmaceutical tablet comprising a shell in which is imbedded two smaller tablets covered by the material of the shell of the pharmaceutical tablet, one of which smaller tablets comprises an NSAID and the other of which smaller tablets comprises misoprostol, whereby the two smaller tablets are not exposed to the environment at the surface of the pharmaceutical tablet, being protected by said shell.

Claim 2 (original): The pharmaceutical tablet of Claim 1 wherein the smaller tablet containing the NSAID is enteric coated.

Claim 3 (original): A pharmaceutical tablet as in Claim 1 or 2 wherein the NSAID is piroxicam.

Claim 4 (original): A pharmaceutical tablet as in Claim 1 or 2 wherein the NSAID is selected from diclofenac and salts thereof.

Claim 5 (original): A pharmaceutical tablet as in Claim 3 wherein the amount of piroxicam is from about 10 mg to about 20 mg.

Claim 6 (original): A pharmaceutical tablet as in Claim 4 wherein the amount of diclofenac or a salt thereof is from about 25 mg to about 75 mg.

Claim 7 (original): The pharmaceutical tablet of Claim 1 or 2 wherein the amount of misoprostol is about 200 µg.

Claim 8 (original): The pharmaceutical tablet of Claim 3 wherein the amount of misoprostol is about 200 µg.

Claim 9 (original): The pharmaceutical tablet of Claim 4 wherein the amount of misoprostol is about 200 µg.

Claim 10 (original): The pharmaceutical tablet of Claim 5 wherein the amount of misoprostol is about 200 µg.

Claim 11 (original): The pharmaceutical tablet of Claim 6 wherein the amount of misoprostol is about 200 μ g.